

Remarks/Arguments

A. Status of the Claims

Claims 10 – 18 and 25 – 31 were elected by Applicants in response to the Requirement for Restriction dated November 14, 2005 and are pending. Claims 1 – 9 and 19 – 24 are withdrawn. Claims 10 – 18 and 25 – 31 are rejected. Claims 11 – 14, 17, and 26 – 30 are amended. Claim 31 is cancelled.

B. Objections

The Examiner has objected to claim 31 as being a substantial duplicate of claim 26. Applicants agree with the Examiner and cancel claim 31.

C. The Claims Are Not Indefinite Pursuant to 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected claims 11, 12, 27, and 28 as being “indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.” Specifically, the Examiner asserts that the broad ranges together with a narrow range or limitation in the same claim is considered indefinite.

Accordingly, Applicants have amended claims 11 and 27 by removing references to ranges for the weight percent of lubricant in the lubricant-solvent solution. The important concept of these claims is that the lubricant is thinned with a solvent, not the exact amount of solvent used. The selection of the amount of solvent used is dependent on many subjective factors and is not critical to the invention.

Similarly, Applicants have amended claims 12 and 28 by removing references to ranges for both the temperature and time of the heating step. The important concept of these claims is that excess solvent is removed by the heating step, not the exact temperature and time of the step. The selection of the heating temperature and the time of the heating step is dependent on many subjective factors and is not critical to the invention.

Applicants contend that amended claims 11, 12, 27, and 28 are now patentable and respectfully request that the 35 U.S.C. § 112 second paragraph rejection of these claims be withdrawn.

D. The Claims Are Not Anticipated by Williams et al. Pursuant to 35 U.S.C 102(b)

Applicants respectfully submit that the Examiner has applied an overly broad and improper interpretation of the Williams patent (U.S. Patent No. 4,822,632). The scope of Williams covers only a specific class of lubricants that are treated with a plasma generated under a limited range of conditions. Williams teaches a surface coated with a lubricant, and that the lubricant is limited to hydrocarbon oils. Illustrative examples provided in Williams include vegetable oil, peanut oil, mineral oil, and the like. Williams further states that the preferred lubricant is a silicone oil, most preferably polydialkylsiloxanes (column 3, lines 38 – 50). Williams also specifies that “in a preferred embodiment of the invention, the lubricant is a low molecular weight silicone oil” and “in the most preferred embodiment, the lubricant is a low molecular weight polydialkylsiloxane” (column 2, lines 42 – 48).

Williams also provides five examples to further describe the scope of the invention (column 5, lines 12 – 68). The lubricants used in these examples were limited to polydimethylsiloxane and polymethyloctylsiloxane. Both of these lubricants are polysiloxanes, and no indication is provided that any lubricants other than those specified (hydrocarbon oils or polysiloxanes) are within the intended scope of the invention. Indeed, the claims are completely limited to silicone compounds (claims 1 and 8 – silicone oil; claim 4 – polydialkylsiloxane; claims 5 and 9 – polydimethylsiloxane).

Thus, it is apparent to one skilled in the art that the scope of the Williams patent is limited to silicone compounds, or in the most broad sense, to hydrocarbon oils. The scope of Applicants’ invention encompasses fluorochemical compounds as well as polysiloxane-based compounds (see paragraph [0044] of the specification). Nowhere does Williams teach the use of fluorochemical compounds as the lubricant, nor would the use of fluorochemical compounds as the lubricant be obvious to one skilled in the art. Indeed, Williams points out that fluorochemical compounds cannot be used and directly teaches against their use: “Polytetrafluoroethylene surfaces provide some reduction in breakout forces, but this material is very expensive, and the

approach has not been totally effective. Thus there is a need for a better method . . . ” (column 2, lines 18 – 21). Accordingly, Applicants have amended claims 13 and 29 to remove the reference to silicone-based compounds, thereby eliminating any possible overlap with the lubricants specified in Williams.

The Examiner further points out that Williams teaches that the lubricant can be exposed to an energy source at any pressure (including atmospheric pressure). Applicants respectfully disagree with this assertion and contend that is an overly broad interpretation that is not supported by the specification or the claims.

Williams teaches the treatment of a lubricant-coated surface with an ionizing gas plasma. As an example of a suitable plasma generator, Williams cites U.S. Patent No. 3,847,652 (the Fletcher patent). Fletcher teaches a plasma generator that operates at 0.05 to 0.6 torr. In contrast, Applicants' invention operates at about 760 torr (atmospheric pressure), or more than 1200 times the highest pressure claimed in Fletcher. Fletcher further describes the plasma apparatus as containing a vacuum pump (FIG. 1), and that typical operating pressure is 0.1 torr (see table, column 4). No indication is given by Williams that the treatment of the lubricant could be carried out at pressures other than extreme vacuum like those necessary to generate a plasma with the Fletcher invention.

Williams teaches that the operating parameters of the plasma generator are a power level of up to about 200 watts at a frequency from about 0.1 to 50 megahertz (column 4, lines 25 – 32). Under these conditions, a plasma can be generated only under conditions of extreme vacuum, such as those specified in Williams: about 0.1 to 1.0 torr (column 4, lines 22 – 23). Additionally, the examples in Williams specify operating pressure within the range of 0.25 to 20 torr. The following reference provides a thorough discussion of the conditions under which a plasma can be generated at both atmospheric pressure and extreme vacuum: Roth, J. Reece. Industrial Plasma Engineering. Volume 2 – Applications to Nonthermal Plasma Processing. Institute of Physics Publishing, Philadelphia, PA. 2001.

Thus, the statement in Williams that “any gas pressure may be used” (column 4, line 20) must be read in context with the plasma generating equipment specified. This equipment can generate a plasma only under conditions of extreme vacuum, and it would not be obvious to one skilled in the art that the Williams invention could be carried out at atmospheric pressure.

As set forth in MPEP § 2131, a claim is anticipated only if each and every element set forth in the claim is found either expressly or inherently described in a single prior art reference. Further, the complete invention must be shown in as complete detail as contained in the claim. The reference to Williams fails to mention or imply in any way that fluorchemical compounds could be used as the lubricant. Williams also fails to specify that the lubricant can be exposed to an energy source at atmospheric pressure. Therefore, Williams fails to anticipate Applicants' claims 10 – 18 and claims 25 – 31 (as amended to remove the overlap with polysiloxane-based lubricants).

In order to satisfy the requirements of 35 U.S.C. 102(b), each and every element of Applicants' claims must be met by the Williams reference. Clearly, each and every element of Applicants' claims is not met by Williams for the reasons given above. It is readily apparent that Applicants have a new and patentably distinct invention not disclosed, taught, or envisaged by Williams.

In conclusion, Applicants submit that the present claims, as amended, are allowable under 35 U.S.C. 102(b) and respectfully request the Examiner to forward this application to issuance at an early date.

E. The Claims Are Not Obvious Under Williams et al. Pursuant to 35 U.S.C. 103(a)

The Examiner rejected claims 10 – 18 and 25 – 31 as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Williams.

To establish a prima facie case of obviousness requires, first, that there be some suggestion or motivation, either in the reference itself, or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference must teach or suggest all the claim limitations.

The reference to Williams, as discussed in Section D of this paper, fails to disclose the use of fluorchemical compounds as the lubricant. In addition, Williams fails to teach that the lubricant can be exposed to an energy source at atmospheric pressure. Nor does Williams provide any suggestion or motivation that the invention can be modified to include the elements

of Applicants' invention. The Williams reference also fails to provide a likelihood of success for the use of fluorochemical compounds exposed to an energy source at atmospheric pressure.

According to MPEP § 2113, the burden is on the applicant to show that a product-by-process claim is not the same as a product of the prior art. Applicants contend that the present invention produces a product that is different and unobvious from Williams.

As established in Section D of this paper, the scope of Williams is limited to the use of silicone-based compounds (or broadly, hydrocarbon compounds) as the lubricant. Silicone-based and hydrocarbon lubricants, when used in medical syringes, have two significant problems well known in the art. The first is a chemical interaction between silicone-based and hydrocarbon lubricants with protein-based and biological-based contents of the syringe. For example, insulin detrimentally reacts with silicon resulting in crystallization of the insulin and formation of particulates in the insulin. Such chemical interactions can result in severe health problems in the user. Consequently, the pharmaceutical industry has long sought silicon-free and hydrocarbon-free lubricated medical devices. Currently, no such devices exist on the market, and Williams does not fill this need. The present invention was specifically designed to overcome this problem. The resulting coating of the present invention contains no silicone compounds (as specified in the amended claims) nor does it contain hydrocarbon compounds; thus, no detrimental chemical reactions occur. Additionally, due to the highly stable nature of the fluorochemical coating produced by the present invention, no detrimental leaching of any other chemical compounds occurs.

The second problem is the migration of the lubricant from between the two sliding surfaces at the point of contact. The treated lubricant of the present invention has been shown to be highly resistant to migration from between sliding surfaces in contact with one another. As shown in Example 9 of the Applicants' specification, no discernable change in performance was observed after allowing the treated surfaces to remain in contact for a period of three days.

The performance characteristics of Applicants' invention are different than what is known in the art for silicone-based lubricants and solves serious problems known in the art. Therefore, the Applicants' invention is different and unobvious from Williams. Applicants submit that the present claims, as amended, are allowable under 35 U.S.C. 103(c) and respectfully request the Examiner to forward this application to issuance at an early date.

F. Clarifications in the Claims

Applicants have amended claims 13 and 29 by adding the phrase “and mixtures thereof” to clarify that mixtures of lubricants can be utilized. Support for this amendment can be found in the specification at paragraph [0046].

Applicants have amended claims 14 and 30 by adding the phrase “and mixtures thereof” to clarify that mixtures of additives can be utilized. Support for this amendment can be found in the specification at paragraph [0048].

Applicants have amended claims 17 and 26 by adding the phrase “and mixtures thereof” to clarify that mixtures of gases can be utilized. Support for this amendment can be found in the specification at paragraph [0049].

G. Conclusion

In view of the foregoing, the claims are now in form for allowance, and such action is hereby solicited. If any point remains in issue which the Examiner feels may be best resolved through a personal or telephone interview, he is kindly requested to contact the undersigned at the telephone number listed below.

All objections and rejections having been addressed, it is respectfully submitted that the present application is in condition for allowance and a Notice to that effect is earnestly solicited.

Respectfully Submitted,

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